June 21, 2002

U.S. Environmental Protection Agency
Docket ID Number OEI-10014
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Room B607
401 M St., SW
Washington, DC 20460

Regulatory Checkbook is a nonpartisan, nonprofit, tax-exempt organization operating under section 501(c)(3) of the Internal Revenue Code. Its mission is to monitor, evaluate and report to the public the extent to which federal regulatory agencies comply with important procedural, analytic and decision-making requirements found in various statutes, Executive orders and guidance documents. These comments are provided to assist you in your effort to craft information quality guidelines for the Environmental Protection Agency (EPA) that fully comply with the provisions of Section 515 of the FY 2001 Consolidated Appropriations Act (P.L. 106-554, "Data Quality Act"). I provided preliminary comments to EPA at its public meeting on May 15, 2002, and also submitted them online via the Agency's anonymous access systems at www.epa.gov/oei/qualityguidelines.[1]

EPA's proposed guidelines[2] do not come remotely close to being consistent with either the law or the government-wide guidelines issued by the Office of Management and Budget (OMB).[3] Indeed, on almost every margin EPA's proposal undercuts OMB's government-wide guidelines and undermines the law.

Following the law, OMB provided agencies the flexibility to tailor these requirements to account for agency-specific differences. This appears to have been terribly naïve. EPA's

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[1] "Preliminary Comments on EPA's Draft Information Quality Guidelines," http://www.epa.gov/oei/qualityguidelines/dockets/iva111.htm.

[2] "Draft Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency," noticed at 67 FR 21234 (April 30, 2002).

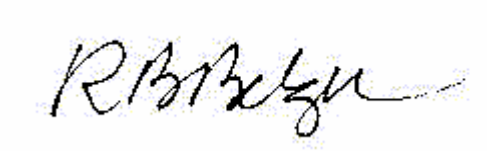
[3] "Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies; Notice; Republication," Office of Management and Budget, 67 FR 8451-8460 (February 22, 2002). See also interim final guidelines at 66 FR 49718 (September 28, 2001) and final guidelines (with numerous typographical errors) at 67 FR 369-378 (January 3, 2002).

proposal abuses the opportunity for implementation flexibility by instead striving to evade all reasonable information quality standards. In many places, EPA's efforts are so brazen as to constitute self-parody. It is extremely difficult to interpret these departures as anything other than systematic evidence of bad faith. The comments enclosed try very hard to resist this temptation.

The information quality standards established by OMB are minimum standards. EPA has no authority to establish standards that are less rigorous or less effective than those promulgated by OMB. In any instance where EPA proposes or adopts a standard that is weaker than OMB's, it simply will not be binding and OMB's default standards will apply. Similarly, OMB's default standards also will apply in any instance where EPA is silent. The law and OMB's guidelines provide agencies with the flexibility to accommodate their own idiosyncratic situations if they choose to do so. OMB cannot compel agencies to take advantage of this discretion if they do not want to exercise it. Nevertheless, OMB lacks the authority to relieve any agency of its obligations under the Data Quality Act.

EPA needs to start anew, this time with a serious and effective management-level commitment to fully comply with the law and OMB's guidelines. If this commitment has been present all along, then it may be necessary to bring in new staff to implement it.

Sincerely,



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Enclosure (1)

COMMENTS ON
U.S. ENVIRONMENTAL PROTECTION AGENCY'S
PROPOSED INFORMATION QUALITY GUIDELINES
DOCKET ID NUMBER OEI-10014

THE PURPOSE OF EPA'S INFORMATION QUALITY GUIDELINES (SECTION 1.1)

EPA's proposed guidelines contain numerous errors in its statement of purpose that undercut OMB's government-wide guidelines and undermine the law.

a. EPA incorrectly claims data quality guidelines are only an internal management tool.

> This document provides guidance to EPA staff and informs the public of EPA's policies and procedures. These guidelines are not a regulation. They are not legally enforceable and do not create any legal rights or impose any legally binding requirements or obligations on EPA or the public. Nothing in these guidelines affects any otherwise available judicial review of EPA action [lines 401-404, emphasis added].

This language fundamentally misinterprets the law and OMB's government-wide implementing guidelines.

The purpose of EPA's guidelines is not to merely "provide guidance to EPA staff and inform[] the public of EPA's policies and procedures." The purpose is to fundamentally change Agency policies and procedures as necessary to ensure that all information disseminated by EPA meets quality standards appropriate to its relative significance and import. This means devising, implementing and verifying the effectiveness of management systems to demonstrate that information disseminated by EPA actually meets these standards. OMB's framework encourages agencies to use or adapt existing systems insofar as they demonstrably achieve statutory objectives. However, it does not authorize them to rely on existing systems that are not designed to achieve information quality standards or which are not effectively implemented.

The Data Quality Act establishes new and higher standards for the quality of information disseminated by federal departments, agencies and commissions. OMB's government-wide guidelines implement the law by establishing minimum government-wide standards that all departments, agencies and commissions must abide by. As OMB clearly states:

> Overall, agencies shall adopt a basic standard of quality (including objectivity, utility, and integrity) as a performance goal and should take appropriate steps to incorporate information quality criteria into agency information dissemination practices. Quality is to be ensured and established at levels appropriate to the nature and timeliness of the information

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> to be disseminated. Agencies shall adopt specific standards of quality that are appropriate for the various categories of information they disseminate (§III.1, emphasis added).

In all references save one, OMB's language is directive and nondiscretionary; the one instance in which OMB uses hortatory language also contains the discretion for agencies to decide for themselves how best to (but not whether to) comply.

The information quality standards established by OMB are minimum standards. EPA has no authority to establish standards that are less rigorous or less effective than those promulgated by OMB. In any instance where EPA proposes or adopts a standard that is weaker than OMB's, it simply will not be binding and OMB's default standards will apply. Similarly, OMB's default standards also will apply in any instance where EPA is silent. The law and OMB's guidelines provide agencies with the flexibility to accommodate their own idiosyncratic situations if they choose to do so. OMB cannot compel agencies to take advantage of this discretion if they do not want to exercise it. Nevertheless, the law and OMB's government-wide guidelines do not permit EPA to alter the fundamental purpose of information quality guidelines, such as converting them into an internal management directive of no legal import.

EPA is correct that its guidelines do not constitute a regulation. The Data Quality Act amended the Paperwork Reduction Act to direct OMB to issue government-wide guidelines so as to improve the quality of information disseminated by the federal government – one of the essential elements of the PRA. The basis for this amendment was Congressional dissatisfaction with the extent to which agencies had complied with the PRA and the degree to which OMB had been able to enforce its provisions. Prior to the Data Quality Act, OMB's authority was generally limited to approving or disapproving agency information collections based on a balancing of practical utility and burden. Subsequent to approval, OMB lacked any authority to ensure that agencies complied with public commitments that were integral parts of the approved action.

EPA is wrong, however, when it asserts that the final guidelines will not be legally enforceable, do not create legal rights or impose legal obligations on EPA. This reading drains the law of content. The Data Quality Act slightly amends the Paperwork Reduction Act, so at a minimum information quality standards are legally enforceable to the same extent as the PRA. In addition, courts will look to see if information quality standards have been violated in their assessment of whether agency actions satisfy requirements of the Administrative Procedure Act. It would be folly to assume that a court will look favorably on an agency action based on information that does not meet information quality standards appropriate to the action's scale, scope and consequences.

b. EPA incorrectly asserts the authority to ignore its guidelines at any time.

> The guidelines may not apply to a particular situation based on the circumstances, and EPA retains discretion to adopt approaches on a case-by-case basis that differ from the guidelines, where appropriate, gray decisions regarding a particular case, matter or action will be made based on applicable statutes, regulations and requirements. Interested parties are free to raise questions and objections regarding the substance of the guidelines and the appropriateness of using them in a particular situation. EPA will consider whether or not the guidelines are appropriate in that situation [lines 404-409].

This language fundamentally misinterprets the law and OMB's government-wide implementing guidelines.

The Data Quality Act and OMB's guidelines apply to all covered information that is disseminated by EPA. The Agency's discretion is limited to tailoring OMB's guidelines to accommodate issues and needs that are idiosyncratic to EPA. As OMB explains in the preamble to its government-wide implementing guidelines:

> OMB sought to avoid the problems that would be inherent in developing detailed, prescriptive, "one-size-fits-all" government-wide guidelines that would artificially require different types of dissemination activities to be treated in the same manner. Through this flexibility, each agency will be able to incorporate the requirements of these OMB guidelines into the agency's own information resource management and administrative practices (67 FR 8452).

In its proposed guidelines, EPA identifies no idiosyncratic needs that justify exercise of the flexibility provided by OMB. Instead, EPA abuses this discretion by brazenly proposing to ignore OMB's government-wide guidelines and the Data Quality Act whenever it happens to be convenient or expedient. It matters not whether EPA concedes that "interested parties are free to raise questions and objections regarding the substance of the guidelines and the appropriateness of using them in a particular situation" [lines 408-409], for they are always free to do so and many will. The Data Quality Act was intended to regulate and constrain federal agencies' conduct so that the information they disseminate meets appropriate quality standards. It was not intended to authorize them to continue disseminating substandard information and immunize them from public criticism and complaint.

c. EPA asserts the authority to modify its guidelines at will, without public notice and comment, without the concurrence of OMB, and without complying with OMB's government-wide guidelines.

> The guidelines are a living document and may be revised periodically to reflect changes in EPA's approach or as we all learn more about how best to address, ensure and maximize

> information quality. EPA welcomes comments on the guidelines at any time and will consider those comments in any future revision of the guidelines [lines 410-413].

This language fundamentally misinterprets the law and OMB's government-wide implementing guidelines.

EPA has no discretion to modify its guidelines in ways that violate the law. EPA cannot reserve to itself unfettered discretion to modify these guidelines without public notice and comment, the concurrence of OMB, or compliance with OMB's government-wide guidelines. Such authority would drain the Data Quality Act and OMB's guidelines of any meaning. EPA's authority to issue agency-specific guidelines is limited and cannot be legally used to emasculate the law on which the guidelines are based.

Statements of intent or purpose are reasonable provided that they are not used to reinvent information quality guidelines for other purposes. This is especially true to the extent that these other purposes may not be fully consistent with the objectives of the Data Quality Act.

WHEN DO THESE GUIDELINES APPLY? (SECTION 1.2)

EPA's proposed guidelines contain numerous errors in its statement of applicability that undercut OMB's government-wide guidelines and undermine the law.

> *a. EPA incorrectly claims the authority to exempt information from meeting all information quality standards based on qualitative factors that it alone decides are sufficient to override the law.*

> Factors such as imminent threats to public health or homeland security, statutory or court-ordered deadlines, or other time constraints, may limit or preclude applicability of these guidelines [lines 418-420, emphasis added].

This restricted scope exceeds the authority conferred on agencies and therefore is inconsistent with OMB's government-wide guidelines. OMB specifically waived timely compliance with information quality guidelines in narrowly crafted circumstances:

> Information quality standards may be waived temporarily by agencies under urgent situations (e.g., imminent threats to public health or homeland security) in accordance with the latitude specified in agency-specific guidelines (67 FR 8460, emphasis added).

Contrary to EPA's proposed language, OMB's waiver is limited only to the timeliness of agency compliance. It is clearly intended only to capture circumstances beyond the agency's control or influence, and even then to assure compliance within a reasonable period of time. An agency that avails itself of this waiver may reasonably delay its compliance with

information quality standards, but it may not legitimately "limit or preclude applicability." OMB's generous provision of a temporary timeliness waiver cannot be construed as the implicit delegation of authority to gut the scope of applicability.

b. EPA incorrectly claims the authority to exempt unspecified third-party information that it disseminates via its web sites.

> Information generally includes material that EPA disseminates from a web page. However not all web page content is considered "information" under these guidelines (e.g. certain information from outside sources) [lines 424-426].

EPA's proposed language is contrary to law and OMB's government-wide guidelines.

EPA proposes an impermissibly broad exemption for "certain" (but undefined) web content. This language would permit EPA to say, "Click here to see what EPA really believes," but exclude the referenced information from Data Quality Act requirements so long as the hyperlink directs the user to an external web site.

EPA should not be held accountable for information in "outside sources" obtained via hyperlinks over which it has no control and about which it cannot reasonably be inferred to represent Agency views. However, EPA's proposed language could be read so broadly as to exclude web links to external sites over which it has complete control. "Certain information from outside sources" is mentioned only as an example of excluded information. More disturbingly, EPA could rely on this language to exclude any information from outside sources that it posts on Agency web sites. Neither reading is consistent with law or OMB's government-wide guidelines.

Whereas EPA proposes that "not all web information is considered 'information' under these guidelines," OMB's government-wide guidelines permit only a very limited exclusion for web content:

> This definition includes information that an agency disseminates from a web page, but does not include the provision of hyperlinks to information that others disseminate [§ V.5].

OMB further narrows the exclusion such that an agency can only exclude from the definition of information such things as opinions where "the agency's presentation makes it clear" that what is "being offered is someone's opinion rather than fact or the agency's views." Thus, if an agency includes a hyperlink to a web site over which it has no control, information on that site is subject to information quality standards unless the Agency "makes it clear" so that a reasonable person cannot conclude that the information contained on the external site has the Agency's endorsement.

c. EPA incorrectly proposes to exempt certain agency-sponsored information.

> EPA disseminates information to the public for purposes of these guidelines when EPA initiates or sponsors the distribution of information to the public.
>
> …
>
> - Agency-sponsored distributions may include instances where EPA reviews and comments on information distributed by an outside party, or adopts or endorses it [lines 427-428, 438-439, emphasis added].

EPA's proposed language in the bullet quoted above is inadequately protective and easily could be abused. The permissive form "may include" actually operates opposite of its appearance -- to improperly exclude certain agency-sponsored disseminations that should always be included. In all cases where EPA adopts or endorses information distributed or disseminated by an outside party, the information in question becomes disseminated by the Agency. There are no exceptions. Information distributed by an outside source can be excluded only if EPA clearly attributes it to this source and uses no language that could reasonably be construed as conferring approval or endorsement.

d. EPA tracks the domain of information considered to be "sponsored" by the Agency.

> EPA disseminates information to the public for purposes of these guidelines when EPA initiates or sponsors the distribution of information to the public.
>
> …
>
> - In general, distributions by outside parties are not considered to be "sponsored" by EPA unless the Agency is using the outside party to disseminate information on the Agency's behalf [lines 427-428, 438-439].

EPA's proposed language tracks OMB's government-wide guidelines. According to OMB, any "agency initiated or sponsored distribution of information to the public" is covered. Further sponsorship "refers to situations where an agency has directed a third-party to disseminate information, or where the agency has the authority to review and approve the information before release" (67 FR 8454). EPA proposes to also include within the scope of applicability any case where the Agency "is using the outside party to disseminate information on the Agency's behalf."

WHAT IS NOT COVERED BY EPA'S PROPOSED GUIDELINES? (SECTION 1.3)

EPA proposes to exclude from its information quality guidelines huge swaths of information that it disseminates

a. EPA improperly proposes to reserve a carte blanche to exclude other unspecified information.

> Items that are not considered information include but are not limited to:
>
> - Internet hyperlinks and other references to information disseminated by others
> - Opinions, where EPA's presentation makes it clear that what is being offered is someone's opinion rather than fact or EPA's views
> - EPA may identify other materials that are not "information" for purposes of these guidelines [lines 447-452, emphasis added].

Certain elements of EPA's proposed language are contrary to the Data Quality Act and OMB's implementing government-wide guidance.

The third bullet in this list would give EPA excessive discretion to exclude unspecified materials from its definition of "information" based on criteria to be determined later and not necessarily revealed. EPA does not have the authority to establish a definition that is materially less expansive than that found in OMB's government-wide guidelines and which, if implemented, would undermine the Data Quality Act. Similarly, EPA does not have the authority to reserve the discretion to make future *ad hoc* determinations that would effectively narrow the definition.

b. EPA improperly proposes to exclude certain information critical to Agency purposes as long as it first disseminated to exempt parties.

> Distribution limited to government employees (EPA and non-EPA) or EPA contractors or grantees: Information distributed only to government employees would not generally be covered by these guidelines because it is not directed to the public. This includes both intra- and inter-agency distribution of information. For example, if EPA wanted to get feedback from a number of other agencies regarding an action it is considering undertaking, the communications between the agencies would not be covered by the guidelines [lines 458-464, emphasis added].

The header to this proposed exemption is much broader than the language that follows. Information distributed exclusively to government employees, contractors or grantees and never subsequently disseminated to the public or used thereafter by the government deserves exemption from information quality standards. However, EPA's proposed language would permit the Agency to distribute information to these parties without complying with otherwise applicable information quality standards for use in developing risk assessments, models, regulatory analyses, and other critical background documents. These documents then could be distributed back to EPA and used for a host of regulatory and programmatic purposes without complying with information quality

standards. If EPA does not intend to craft such a loophole, then it needs to provide clear, meaningful examples of situations in which a non-public distribution would still be subject to its guidelines. For example, in addition to clear language prohibiting the use of this exemption to circumvent information quality standards, EPA also needs to make clear that the exemption does not apply in any case where EPA or any of its agents distributes information to a State or other co-regulator, or to a public interest group for subsequent dissemination.

EPA's stated basis for this exemption creates additional concerns. Whether or not information is "directed to the public" is an irrelevant factor in determining whether it ought to be covered by information quality guidelines. Obvious examples include information directed to Members of Congress, States and other co-regulators, and public interest groups. It is inconceivable that Congress intended for agencies to ignore otherwise applicable quality standards when they provide information to Members, standing committees, and the leadership. It is similarly unimaginable that Congress intended federal agencies to be able to escape information quality standards by using States and other co-regulators or public interest groups as intermediaries for the dissemination of substandard information.

c. EPA improperly proposes to exclude a wide swath of information whose dissemination is clearly intended to influence public policy and private decisionmaking.

> Distribution of information in correspondence with individuals or persons: These guidelines do not apply to any correspondence with individuals or persons, regardless of format. "Persons" for purposes of this provision includes any individual or person, including a partnership, association, corporation, business trust, legal representative, organized group of individuals, State, territorial, tribal, or local government or branch thereof, a political subdivision of a State, territory, tribal, or local government or a branch of a political subdivision, or any federal governmental branch including members of Congress and their staff [lines 475-481].

EPA's proposed definition of "person" is a misappropriation of the definition found in OMB's Paperwork Rule at 5 CFR 1320.3(k). The expansive definition of "person" in the Paperwork Rule protects the public by constraining agencies' powers to impose burdens. Here, EPA's proposed language does precisely the opposite. It expands agency powers by excluding from information quality standards virtually most written communications by the Agency. OMB's government-wide information quality guidance strikes a reasonable and appropriate balance by excluding information where "distribution [is] limited to correspondence with individuals or persons" (§ V.8, emphasis added). By restricting the scope of the exception, OMB permits agencies substantial latitude to communicate without unwittingly creating an incentive to use such communications to evade information quality standards. EPA's proposed language omits this "limited to" construction.

The Data Quality Act contains no authority for agencies to exclude broad categories of information it disseminates merely based on the identity of the intended or nominal recipient. Recipient identity-based information quality standards are inherently discriminatory, for they confer protection to certain members of the public and not others.

As a practical matter, it seems especially peculiar for EPA to seek to exclude from information quality standards all communications with the Congress. A case can be made that certain congressional communications are not "disseminations" of information that Congress would expect to be covered. Similarly, many congressional communications are non-substantive or could contain information that has satisfied information quality standards in other contexts. Nevertheless, some congressional communications are highly substantive and imbued with important, policy-relevant informational content.

Generally, information disseminated in congressional communications should be exempt only insofar as it is not simultaneously disseminated to the public. Frankly, it seems foolhardy for EPA to try to create any exemption for congressional communications, for Congress may respond by insisting that all Agency congressional communications meet the highest information quality standards. Surely this would leave EPA worse off than if it had not tried to finesse the issue.

d. EPA's proposed exclusion of press releases appears to correctly apply the discretion provided by OMB in its government-wide guidance, but serious issues lurk in the background.

> Distribution of information in press releases and similar announcements: These guidelines do not apply to press releases, fact sheets, press conferences or similar communications in any medium that announce, support the announcement or give public notice of information EPA has disseminated elsewhere [lines 482-485].

The intended meaning of EPA's proposed language is not entirely clear, but the Agency's language can be interpreted in a manner that is consistent with OMB's government-wide guidelines. The critical interpretative issue is whether the concluding prepositional phrase ("of information EPA has disseminated elsewhere") implies that such dissemination occurred in compliance with applicable information quality standards. This interpretation is a reasonable one, but it is not the only interpretation possible because it is not explicitly included in EPA's language. EPA should clarify its intent by stating clearly that information the Agency "has disseminated elsewhere" must have met applicable information quality standards when disseminated.

It would be inappropriate to exempt press releases and similar communications if the information they contain was disseminated elsewhere but not in compliance with applicable information quality guidelines. Press releases, fact sheets and "similar communications"

should not be exempt from the definition of "dissemination" if they contain errors or information that is covered if disseminated in another form.

Further, EPA must clarify that information quality standards apply if the otherwise exempt communication includes any material modification of information that elsewhere met applicable information quality standards. Otherwise, press releases, fact sheets and the like could be exempt but convey different messages than the information upon which they are based.

e. EPA's proposed exemption of information distributed in public filings would impermissibly include information created, sponsored or endorsed by States and other co-regulators.

> Distribution of information in public filings: Public filings include information submitted to EPA by any individual or person (as defined above). The guidelines do not apply where EPA distributes this information simply to provide the public with quicker and easier access to materials submitted to EPA that are publicly available. This will generally be the case if EPA has not authored the filings, and is not distributing the information in a manner that suggests that EPA endorses or adopts the information, and EPA does not indicate in its distribution that it is using or proposing to use the information to formulate or support a regulation, guidance, or other Agency decision or position [lines 507-514].

In most cases, information that EPA receives from individuals and "persons" submitted to the Agency ought to be exempt from information quality standards. Because EPA's proposed definition of "person" is so expansive, however, that its proposed exemption for public filings is far too broad. For example, States and other co-regulators are covered within EPA's proposed definition of "person." Therefore, EPA's proposed public filings exemption would exclude information that EPA receives from States and other co-regulators that it must rely upon either to make independent decisions or to approve decisions make by co-regulators. EPA must exclude from this exemption any information that it receives from States and co-regulators unless this information concerns their status as regulated parties.

f. EPA improperly proposes to exempt itself from information quality standards when it submits public filings.

> Information in public filings submitted by EPA to other agencies or governmental agencies, such as public comments EPA submits in a state rulemaking, also would not be covered by these guidelines [lines 525-527].

This proposed exemption is contrary to the Data Quality Act and inconsistent with OMB's government-wide implementing guidelines. It would exempt EPA from having to meet information quality standards when it provides official, authoritative information to

other government agencies, including both sister federal agencies and co-regulators such as States and regional pollution control districts. As written, this exemption also could extend to filings EPA makes pursuant to its review authorities under the National Environmental Policy Act.

EPA appears to have misread both the language and the intent of OMB's limited exclusion from the definition of "dissemination." The clear purpose of OMB's language is to exclude from information quality standards public filings received by EPA and for which it could not and should not be held accountable. The Agency proposes to transform this obvious, sensible and non-controversial exclusion into a major loophole by which EPA can escape the provisions of the Data Quality Act for what are in some cases the most important of all disseminations the Agency makes.

Information contained in official, authoritative public filings to other government agencies – especially to those with which EPA has a co-regulator relationship – ought to meet the highest of information quality standards. Exempting these disseminations communicates to recipient government agencies (and the public) that information contained in them is neither valid nor reliable. If EPA finalizes language along these lines, then recipients of these communications would be well advised not to rely upon them. For example, any co-regulator that makes decisions based on an EPA public filing that the Agency exempted from information quality standards runs a serious risk that its actions will be successfully challenged on the ground that EPA's conscious decision to exclude its public filings signals that information contained in them is not trustworthy.

g. EPA proposes to misuse OMB's adjudicative processes exemption to exclude from coverage a host of regulatory actions for which the Data Quality Act clearly applies.

EPA's proposed language misapplies OMB's adjudicative process exemption to a host of situations for which it has no relevance and which ought to be fully subject to information quality standards:

> Distributions of information related to subpoenas or adjudicative process are not covered by these guidelines… This includes:
>
> …
>
> c. Distribution of information in documents related to any formal or informal administrative action determining the rights and liabilities of specific parties, including documents that provide the findings, determinations or basis for such actions. Examples include the processing or adjudication of applications for a permit, license, registration, waiver, exemption, or claim; actions to determine the liability of parties under applicable statutes and regulations; and determination and implementation of remedies to address such liability [lines 528-529, 538-544, emphasis added.]

EPA states that its implementation of OMB's adjudicatory process exemption is limited to situations in which there are "well-established procedural safeguards and rights to address the quality of adjudicatory decisions and provide persons with an opportunity to contest decisions" [lines 531-533]. However, EPA's numbered list of examples contains the item cited above. The array of actions referenced here is substantially broader than mere "adjudicatory processes" for which substantially equivalent protections already exist. Whereas OMB's objective was to avoid redundancy and deny parties unintended additional legal remedies, EPA proposes to pretend that "any formal or informal administrative action" already contains these protections (emphasis added).

OMB's adjudicatory processes exemption applies only to those existing procedures in which an equivalent level of public protection on information quality matters is assured. For every adjudicatory process that EPA believes warrants this exemption, the Agency must document and demonstrate how that process achieves equivalent protection. EPA should abandon its effort exempt entire classes of official acts for which the Data Quality Act establishes these protections for the first time.

HOW EPA PROPOSES TO ENSURE AND MAXIMIZE THE QUALITY OF DISSEMINATED INFORMATION (SECTION 3.1)

EPA proposes language merely asserting that the Agency fully achieves the objectives of the Data Quality Act through the application of various internal management systems:

> EPA ensures and maximizes the quality of information by using policies and procedures well established within the Agency as appropriate to the information product. There are many tools that the Agency uses such as the Quality System[9], review by senior management, peer review process, communications product review process, the web guide, and the error correction process. The Agency uses a graded approach and uses these tools based on the intended use of the information and the resources available. As part of this graded approach, EPA recognizes that some of the information it disseminates includes influential scientific, financial, or statistical information, and that this category should meet a higher standard of quality [lines 581-588, footnotes omitted].

EPA provides no evidence that the internal management systems it cites were designed to achieve the purposes of the Data Quality Act; no evidence that they actually achieve these purposes in practice; and no evidence that they satisfy the procedural safeguards set forth in OMB's government-wide guidelines.

If EPA issues final guidelines that rely on these internal management systems, then the Agency should be prepared for rigorous examination of their information quality provisions and demanding public oversight of their implementation. Most (if not all) of these systems were established before the Data Quality Act was passed, so it is highly

unlikely that they can satisfy statutory requirements without significant amendment. In the event that they can, then EPA will need to quickly modify procedures (subject to public notice and comment) so as to infuse them with pre-dissemination review procedures, opportunities for active public participation, and an objective and effective error corrections mechanism.

EPA seems to be inclined to rely on peer review as its device for meeting applicable information quality standards, especially those for influential information. This approach will fail because peer review has never been intended to ensure that information quality standards are met. OMB specifically required that agency peer review practices meet certain performance standards:

> If agency-sponsored peer review is employed to help satisfy the objectivity standard, the review process employed shall meet the general criteria for competent and credible peer review recommended by OMB-OIRA to the President's Management Council (9/20/01) (http://www.whitehouse.gov/omb/inforeg/oira_review-process.html), namely, "that (a) peer reviewers be selected primarily on the basis of necessary technical expertise, (b) peer reviewers be expected to disclose to agencies prior technical/policy positions they may have taken on the issues at hand, (c) peer reviewers be expected to disclose to agencies their sources of personal and institutional funding (private or public sector), and (d) peer reviews be conducted in an open and rigorous manner" (§V.3.b.i, excerpt).

It is not clear that EPA's peer review program complies with these performance standards, especially when additional criteria contained in the memorandum to the President's Management Council but not included in OMB's excerpt, are considered. Many Agency peer review practices are not at all external. Others are not truly independent because peer reviewers are selected by EPA management or subject to EPA veto, or they provide EPA staff with nonpublic early drafts of their reports. Disclosures typically are limited to private financial interests only. Finally; many EPA peer reviews do not even comply with the minimum standards for openness set forth by the Federal Advisory Committee Act.

Just one example is sufficient to demonstrate why EPA's existing peer review procedures fall short of both meeting OMB's performance standards. In January 2002, EPA disseminated for external review a draft risk assessment for perchlorate. A peer review panel was selected by an Agency contractor, thus nominally satisfying OMB's requirement for peer reviews to be both external and independent. However, all contractor-led peer reviews are exempt from FACA and thus lack the requisite openness required by OMB. There is no public evidence that compliance with OMB's disclosure requirements occurred, and at least one member of the panel appears to have had a significant conflict of interest.

The risk assessment that was the subject of this peer review failed to meet the quality standard for influential information. One can leave aside the scientific merits of the document and still conclude that the internal management systems which EPA says "ensure and maximize" quality failed utterly in practice. The draft risk assessment contains no references at all about information quality; no evidence of pre-dissemination review of information quality issues; and no compliance with the basic information quality standards set forth by the Safe Drinking Water Act. EPA can reply that its January 2002 draft perchlorate risk assessment was not covered by information quality standards because it was disseminated prior to October 1, 2002. This is surely correct. However, EPA cannot argue that information quality standards do not apply to the draft risk assessment yet simultaneously claim that its existing internal management systems "ensure and maximize" information quality.

The report of the perchlorate peer review panel has not been publicly disclosed as of this date. In any event, OMB has clearly stated that peer review is not a substitute for a persuasive demonstration that information quality standards are met. This is especially true with respect to influential information:

> The fact that the use of original and supporting data and analytic results have been deemed "defensible" by peer-review procedures does not necessarily imply that the results are transparent and replicable (67 FR 8455).

Transparency and replicability are essential attributes of the objectivity standard, not because they demonstrate objectivity but because they make such a demonstration feasible. Peer review is a substitute for neither.

HOW EPA PROPOSES TO DEFINE "INFLUENTIAL" INFORMATION (SECTION 3.2)

EPA proposes a categorical approach for information that is "influential" according to the definition provided by OMB in its government-wide guidelines. There are significant inherent problems with this categorical approach. EPA states only that information in these categories "<u>should</u> adhere to a higher standard of quality" [line 595, emphasis added], but includes no requirement that it actually does. By listing these specific categories as falling within the scope of influential information, EPA also implies the exclusion of categories that it does not list. Finally, EPA may be trying to claim that certain internal management systems (*e.g.,* peer review) ensure the achievement of higher information quality standards even though these systems were not designed and are not currently implemented to achieve information quality objectives.

a. EPA's proposed use of categorical information quality standards improperly ignores informational content.

EPA's proposed approach to determining appropriate information quality standards in lines 590-628 is unworkable, ineffective and susceptible to abuse. A categorical approach in which specific standards apply to all disseminations within a category does not account for how informational content may vary within each category. For example, an economically significant regulatory action will surely contain "influential" information for which the highest quality standards should apply. However, because not all information contained in such an action will be influential, subjecting all covered information within it to the highest standards would be inappropriate as well as impractical. Conversely, there could be many Agency disseminations in categories other than those identified by EPA in lines 596-628 containing influential information for which the highest standards ought to apply. Hence, EPA's categorical approach will be unworkable and ineffective in practice.

Such an approach also will be susceptible to abuse. If EPA establishes categories that would not normally be subject to high information quality standards, the Agency will unwittingly create perverse incentives for these categories to be misused as vessels for the dissemination of influential information outside of the information quality guidelines otherwise applicable to such information.

A reasonable use of a categorical approach is to establish defaults which require the application of high information quality standards unless a persuasive case can be presented why such standards should not apply. The burden of proof ought to be relatively high and rise as the importance of the information in question rises. For categories in which the default information quality standard is low, a very low burden of proof ought to be sufficient to show that a higher standard is more appropriate. Moreover, EPA needs a public process whereby outside parties can provide the necessary evidence. Like any other agency, EPA has an inherent conflict of interest that argues against a scheme whereby the Agency alone judges its own work.

b. EPA's proposed definition of "top Agency actions" is vague and impossible to monitor externally.

> Information disseminated in support of top Agency actions (i.e., rules, substantive notices, policy documents, studies, guidance) that demand the ongoing involvement of the Administrator's office and extensive cross-Agency involvement; issues have the potential to result in major cross-Agency or cross-media policies, are highly controversial, or provide a significant opportunity to advance the Administrator's priorities. May also include precedent setting or controversial science or economic issues [lines 597-602].

There is surely no argument that "top Agency actions" ought to be subject to the quality standards appropriate for influential information. However, EPA does not clearly state what constitutes a "top Agency action." The signature of the administrator, deputy administrator, or an assistant administrator apparently is not enough. The "ongoing involvement" of the administrator's office is required, but identical involvement by the deputy administrator or an assistant administrator would not. Whether the "ongoing involvement" of the administrator's staff qualifies also is left unclear. Finally, EPA offers no independently observable measure of the frequency, intensity or duration of involvement that would trigger designation as a "top Agency action."

If EPA wants to adopt a categorical approach for inclusion within the standard for influential information, then categories ought to be devised such that the highest information quality standards automatically apply. Any action requiring the signature of an officer of the United States Government ought to be presumptively covered. Information within these actions could be excluded based on a substantial showing that it is not influential.

c. EPA's proposed inclusion of "economically significant" regulatory actions implicitly and inappropriately excludes "significant" regulatory actions.

> As defined in Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993), Agency actions that are likely to have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities [lines 603-608].

EPA is correct that much information contained in or supporting an economically significant regulatory action should meet the higher quality standard for influential information. The significance of EPA's approach, however, lies in what the Agency implicitly excludes – information contained in significant regulatory actions. There is no credible basis for making the distinction EPA proposes to make. According to OMB, information is influential if "the agency can reasonably determine that dissemination of the information will have or does have a clear and substantial impact on important public policies or important private sector decisions" (67 FR 8460). Under EPA's proposed definition, only economically significant regulatory actions constitute "important public policies" with "clear and substantial impact." If that is the case, then the distinction between significant and economically significant is one without a difference, and OMB ought to determine that all EPA regulatory actions are economically significant for information quality purposes.

d. EPA's proposed inclusion of "work products undergoing peer review" implicitly and inappropriately excludes from the domain "influential" scientific and technical information that does not undergo peer review.

> As called for under the Agency's Peer Review Policy, major scientific and technical work products and economic analysis used in decision making. Scientific and technical work products that are used to support a regulatory program or policy position and that meet one or more of the following criteria are candidates for peer review: establishes a significant precedent, model, or methodology; addresses a significant controversial issue; focuses on a significant emerging issue, has significant cross-Agency implications; involves a significant resource investment; uses an innovative approach; or has a statutory or other legal mandate for peer review. Also includes major economic analyses such as internal Agency guidance for conducting economic and financial methodologies that will serve as a principal method or protocol used to conduct economic analyses within a program; unique or novel applications of existing economic or financial methodologies; broad-scale economic assessments of regulatory programs such as those required by Congressional mandates; and, new stated preference or revealed preference surveys developed to assist in the economic analysis of a regulation or program [lines 609-623].

EPA is surely correct that any scientific and technical information warranting peer review ought to be subject to the higher quality standard applicable to influential scientific and technical information. However, EPA's peer review policy does not require external, independent peer review for a substantial body of influential scientific and technical information. The Agency's policy is necessarily selective and resource constrained, and because it was written long before the Data Quality Act was passed it could not have been designed to achieve the objectives of this statute.

Further, it is inappropriate for EPA to assume that scientific and technical information that it chooses not to subject to peer review is *per se* not influential. EPA seems to be trying to shoehorn information quality issues into an existing internal management system that is poorly equipped for the task of achieving the higher quality standard that applies to influential scientific and technical information.

e. EPA's proposal to make case-by-case determinations that disseminations contain "influential" information lacks a transparent and effective mechanism for making these determinations, and the criteria necessary to implement one.

> The Agency may make determinations of what constitutes "influential information" beyond those classes of information already identified on a case-by-case basis for other types of disseminated information that will have or do have a clear and substantial impact (i.e. change or effect) on important public policies or important private sector decisions [lines 624-628].

EPA's proposed categorical approach makes case-by-case determinations necessary, for no categorical approach can accommodate the rich variety of situations that appear in

practice. The problem with EPA's case-by-case approach is that it lacks a transparent mechanism for making case-by-case determinations. EPA does not disclose the criteria that it would use to make these determinations, so its actions could not be reproducible. These are essential features of an effective procedure for making case-by-case determinations. Without such a procedure, each case-by-case determination (or non-determination) could be subject to controversy and challenge and its categorical approach will fail.

HOW EPA PROPOSES TO ENSURE AND MAXIMIZES THE QUALITY OF "INFLUENTIAL" INFORMATION (SECTION 3.3)

a. EPA proposes to substitute transparency for quality in its higher standard for "influential" information.

> It is important that analytic results have a high degree of transparency regarding (1) the source of the data used, (2) the various assumptions employed, (3) the analytic methods applied, and (4) the statistical procedures employed. It is also important that the degree of rigor with which each of these factors is presented and discussed be scaled as appropriate, and that all factors be presented and discussed [lines 633-637].

EPA is correct that transparency is important; indeed, it is a critical element of OMB's reproducibility standard. Nevertheless, transparency *per se* is not a substitute for quality, which is what EPA's description of its proposed higher standard for influential information appears to be. A commitment to fully disclose data, assumptions, analytic methods and statistical procedures certainly should be applauded. However, merely "showing one's work" – however fundamental this may be to scientific endeavor – is not the same thing as demonstrating high quality.

OMB's government-wide guidelines state that "agency guidelines shall include a high degree of transparency about data and methods to facilitate the reproducibility of such information by qualified third parties" (67 FR 8460). That is, transparency is a critical attribute of influential information so that the applicable quality standard can be independently verified. Contrary to EPA's proposed approach, it is not equivalent to the quality standard itself. EPA cannot use transparency as a shield to protect it from applicable quality standards. Transparency is a necessary condition for meeting the reproducibility test of objectivity. But, transparency is not sufficient to show reproducibility, and reproducibility *per se* is not *prima facie* evidence of either objectivity or satisfaction of the higher quality standard applicable to influential information.

b. EPA proposes to evade compliance with OMB's requirement for robustness checks in cases where transparency is not feasible.

OMB's government-wide guidelines provides a mechanism for demonstrating that the high quality standard for influential information has been met in those rare cases where "compelling interests" prevented transparency from ensuring reproducibility. In these cases, OMB said that "agencies shall apply especially rigorous robustness checks to analytic results and document what checks were undertaken" (67 FR 8460, emphasis added). However, EPA proposes to comply with OMB's directive only when it is convenient to do so:

> [I]f access to data and methods cannot occur due to compelling interests such as privacy, trade secrets, intellectual property, and other confidentiality protections, EPA should to the extent practicable, apply robustness checks to analytic results and document what checks were taken [lines 637-640, emphasis added].

EPA's proposed language removes the teeth from the OMB guidelines. First, EPA says nothing about whether the robustness checks it will perform will be "especially rigorous." Presumably, any robustness checks will do. Second, these checks will only be applied to the extent "practicable." Unlike the term "practical," which permits one to stop when further actions are reasonably judged to be infeasible, the term "practicable" also includes an element of cost. Therefore, EPA proposes to avoid imposing on itself any duty to perform robustness checks that it alone judges to be too costly.

Finally, EPA proposes to supplant OMB's requirement to perform robustness checks (*i.e.,* "shall apply") with hortatory language (*i.e.,* should … apply"). It's as if EPA feared that a circumstance might arise in which even the most trivial robustness checks could be expected, and determined to ensure that it had the discretion to evade all such requirements all the time.

In any event, EPA's proposed language limiting (and possibly eliminating) the use of robustness checks is clearly inconsistent with OMB's government-wide guidelines. Not only does OMB expect "especially rigorous" robustness checks to be applied in the case of influential information for which the reproducibility standard cannot be met, OMB also established a government-wide policy stating that peer review is not a substitute for robustness checks:

> For information likely to have an important public policy or private sector impact, OMB believes that additional quality checks beyond peer review are appropriate (67 FR 8455).

c. EPA improperly proposes to assert that information it disseminates satisfies the high quality standard applicable to "influential" information even if underlying components do not.

> Original and supporting data may not be subject to the high and specific degree of transparency required of analytic results; however, EPA should apply relevant Agency policies and procedures to achieve reproducibility to the extent practicable, given ethical, feasibility, and confidentiality constraints [lines 633-643, emphasis added].

This language misreads OMB's government-wide guidelines on several margins. OMB gave specific direction as to the extent to which information quality standards applied to original and supporting data. OMB said that agencies could not require all original and supporting data meet the same (high) standard that applied to agency-disseminated analytic results:

> With regard to original and supporting data related thereto, agency guidelines shall not require that all disseminated data be subjected to a reproducibility requirement (§V.3.b.ii.A, excerpt).

To resolve this balancing act, OMB directed agencies to consult broadly with expert bodies and organizations to inform their determinations of the extent to which transparency could be achieved, and provide this information in their proposed guidelines:

> Agencies may identify, in consultation with the relevant scientific and technical communities, those particular types of data that can practicable be subjected to a reproducibility requirement, given ethical, feasibility, or confidentiality constraints (§V.3.b.ii.A, excerpt).

> OMB … asks that agencies consider, in developing their own guidelines, which categories of original and supporting data should be subject to the reproducibility standard and which should not. To help in resolving this issue, we also ask agencies to consult directly with relevant scientific and technical communities on the feasibility of having the selected categories of original and supporting data subject to the reproducibility standard (67 FR 8455-8456).

> When agencies submit their draft agency guidelines for OMB review, agencies should include a description of the extent to which the reproducibility standard is applicable and reflect consultations with relevant scientific and technical communities that were used in developing guidelines related to applicability of the reproducibility standard to original and supporting data (67 FR 8456).

EPA's proposed language does not fulfill any of these expectations. The Agency discloses no evidence of the consultations OMB expected and fails to illuminate the extent to which original and supporting data must be highly transparent. Equally disconcerting, EPA says only that it "should apply relevant Agency policies and procedures to achieve

reproducibility to the extent practicable" (emphasis added). That is, only to the extent that its existing internal management systems achieve reproducibility would EPA be obligated to accomplish this fundamental objective – an obviously circular result. These systems need not work too hard because they would only need to be used "to the extent practicable."

EPA's language permits the Agency to claim that information meets the high standard applicable to influential information even if "original and supporting data" do not meet any applicable information quality standards at all. Thus, EPA might conclude that an influential risk assessment met the high standard applicable to influential information even if original and supporting data did not. It is hard to imagine how such an approach could work effectively. In manufacturing, the quality of a product cannot be maintained if its components are flawed, adulterated or contaminated. Information products are no different; the quality of the final product cannot be better than the quality of its separable parts.

d. EPA lacks a reasoned application of OMB's reproducibility requirement to original and supporting data.

EPA's language in section 3.3 is so vague as to be uninterpretable. Public commenters can only speculate as to what the Agency intends. An uncharitable reading suggests that no original or supporting data would be subject to the reproducible requirement, or that EPA intends to shift the burden of meeting this requirement to regulated parties that are obligated by other statutes or regulations to submit data.

OMB clearly intended that agencies rely on original and supporting data that are "objective":

> In addition, "objectivity" involves a focus on ensuring accurate, reliable, and unbiased information. In a scientific, financial, or statistical context, the original and supporting data shall be generated, and the analytic results shall be developed, using sound statistical and research methods (§V.3.b, excerpt).

Nevertheless, it seems unlikely that OMB also intended to delegate to agencies the authority to shift the burden of satisfying information quality standards to others. Generally, it would be an abuse of an agency's authority to use its secondary and derivative use of original and supporting data as leverage for imposing additional burdens on those who generate these data. Independent parties cannot be compelled to produce data that meet agency needs. In many instances, however, regulated parties can be so compelled, so the existing ICR process under the Paperwork Reduction Act is the appropriate venue for weighing the additional burden of such demands against the practical utility to the agency. Information quality ought to be a fundamental element of each information collection request that EPA submits to OMB for review. Moreover, in every case in which EPA disseminates information obtained through an approved information collection request, EPA should document that it had

complied with all material provisions of applicable supporting statement and research protocols. Such documentation would ensure that, at the time EPA intends to disseminate it, this information meets applicable information quality standards.

A reasonable application of the reproducibility requirement takes account of (1) who generated the original and supporting information and (2) how an agency proposes to utilize it. To the extent possible, an agency should rely on original and supporting data whose quality is appropriate for the agency's intended use. This is what is meant by OMB's statements scaling the intensity of the applicable information quality standard to the stakes involved:

> The more important the information, the higher the quality standards to which it should be held, for example, in those situations involving "influential scientific, financial, or statistical information" (a phrase defined in these guidelines). The guidelines recognize, however, that information quality comes at a cost. Accordingly, the agencies should weigh the costs (for example, including costs attributable to agency processing effort, respondent burden, maintenance of needed privacy, and assurances of suitable confidentiality) and the benefits of higher information quality in the development of information, and the level of quality to which the information disseminated will be held (67 FR 8452-8453).

Where original and supporting data do not meet standards appropriate for the agency's intended use – and superior data that meet these standards are not available – then the agency should fully disclose both the extent to which original and supporting data do not meet appropriate information quality standards and the implications of these limitations.

Where original and supporting data are generated by the agency itself (or its agents and contractors), then the applicable information quality standard for these underlying data should be based on the highest, most intensive application for which the agency intends to use them. It is difficult to muster a justification for an agency knowingly utilizing data that it collected based on (say) a basic standard of quality when it intended for these data to be influential.

e. EPA proposes to limit the high quality standard applicable to "influential" information to only those cases where it is achieved.

A fundamental defect of EPA's proposal is it merely asserts that existing internal management systems already achieve statutory objectives:

> EPA has several Agency-wide and Program- and Region-specific policies and processes which the Agency applies to ensure and maximize the quality of influential information. Agency-wide processes of particular importance to ensure the quality, objectivity, and transparency of influential information are the Agency's Quality System, Action Development Process, Peer Review Policy, and related procedures. Many influential

> information products may be subject to more than one of these processes [lines 644-648, emphasis added].

EPA's language has a certain circular quality to it: Information that meets applicable information quality standards through the application of these internal management systems is subject to the Agency's information quality guidelines, but information that does not meet these standards appears to be exempt.

Only those human health risk assessments "that have been categorized as influential" are potentially subject to the higher standard for influential scientific and technical information. Presumably, this excludes any human health risk assessment that the Agency decides not to subject to peer review. For example, the vast majority of entries in EPA's Integrated Risk Information System were not peer reviewed in accordance with the Agency's Peer Review Policy. They could be exempt because they were not peer reviewed – and hence circularly defined as "not influential" irrespective of the extent to which they "will have or do[] have a clear and substantial impact on important public policies or important private sector decisions." Of course, this ignores the problem that peer review, at best, can achieve only basic information quality and cannot meet the higher standard applicable to influential information.

HOW EPA PROPOSES TO ENSURE AND MAXIMIZES THE QUALITY OF "INFLUENTIAL" RISK-RELATED INFORMATION (SECTION 3.4)

EPA proposes to "adapt" the basic quality standards of the Safe Drinking Water Act rather than adopt them, and the Agency's proposed adaptation is perverse. Lines 657-682 appear to faithfully state the applicable statutory language, but they include temporizing clauses that undercut the SDWA language on all fronts. If finalized as proposed, the SDWA basic quality standard could apply only to those actions the Agency takes pursuant to the Safe Drinking Water Act (and for which it already faces a statutory obligation anyway).

> With respect to influential scientific information regarding human health risk assessments, EPA should ensure, to the extent practicable and in conformance with Agency guidelines, the objectivity of this information disseminated by the Agency by adapting the quality principles found in the SDWA Amendments of 1996:
>
> (A) The substance of the information is accurate, reliable and unbiased. This involves the use of,
>
> (i) the best available, peer-reviewed science as appropriate, and supporting studies conducted in accordance with sound and objective scientific practices; and
>
> (ii) data collected by accepted methods or best available methods (if the reliability of the method and the nature of the decision justifies the use of the data).

> (B) The presentation of information on human health effects, is comprehensive, informative, and understandable. In a document made available to the public, EPA should specify –
>
> (i) each population addressed by any estimate of applicable human health effects;
>
> (ii) the expected human health risk or central estimate of human health risk for the specific populations affected;
>
> (iii) each appropriate upper-bound or lower-bound estimate of human health risk;
>
> (iv) each significant uncertainty identified in the process of the assessment of human health effects and studies that would assist in resolving the uncertainty; and
>
> (v) peer-reviewed studies known to the Administrator that support, are directly relevant to, or fail to support any estimate of human health effects and the methodology used to reconcile inconsistencies in the scientific data [lines 657-682, emphasis added].

a. EPA proposes to evade the statutory language of the Safe Drinking Water Act for risk-related information.

The basic information quality standard established in the Safe Drinking Water Act has both substantive and presentation components. OMB has adopted both components in its government-wide guidelines as default basic information quality standards for risk-related information. EPA is the federal agency that issues SDWA regulations and is therefore obligated by law to meet them in some cases and is most capable of applying them elsewhere. Inexplicably, EPA proposes not to adopt the SDWA standards for risk-related information. Instead, EPA proposes to adapt them in ways that substantially diminish their stature and weaken their effect.

EPA proposes to adapt the information quality standards of the Safe Drinking Water Act Amendments of 1996 by making them merely hortatory. This is accomplished by applying a host of debilitating caveats. "EPA should ensure" that the risk assessment adheres to the quality principles of the Safe Drinking Water Act, but need do so only "to the extent practicable and in conformance with Agency guidelines," the latter qualification being especially opaque. In EPA's proposed adaptation the "best available, peer-reviewed science" matters only "as appropriate." EPA offers no hint as to when the best available peer-reviewed science is not appropriate, but the Agency can be presumed to have situations in mind (though not disclosed) because otherwise this caveat would be superfluous.

OMB established the SDWA language as a default government-wide standard for basic quality. EPA has the discretion to adapt this language, but it must justify the specific adaptations it proposes to make. EPA's proposed guidelines do not provide such a justification.

b. EPA proposes to transform the information quality language in the Safe Drinking Water Act so as to authorize the use of demonstrably inferior scientific and technical information.

> In applying these principles, "best available" refers to the availability at the time an assessment was made, and that in some situations, the Agency may need to weigh the resources needed and the potential delay associated with gathering additional information in comparison to the value of the new information in terms of its potential to improve the substance of the assessment [lines 677-680, emphasis added].

EPA proposes to give itself two additional and substantial loopholes from the applicability of the basic quality standard contained in the SDWA. First, EPA proposes to meet applicable information quality standards only "at the time an assessment was made." EPA would have no obligation to use the "best available" science at the time it disseminates scientific information. This loophole implies that there is truth in the aphorism that mediocrity is "good enough for government work." It would generally deter the Agency from keeping up with scientific advancements, for to do so could increase its burdens. Years could pass after a risk assessment had been performed and EPA would have no obligation to update it before using it as the basis for policy decisions. Scientific information that is universally regarded as fundamentally wrong could nevertheless satisfy applicable information quality standards as long as the information in question had been obtained when it was believed to be correct.

This loophole also would systematically bias the Agency's investments in scientific discovery in favor of developments in which it was institutionally interested. Generally, scientific advancements suggesting that risks were higher than previously thought could get greater attention than advancements indicating that risks were not as great as previously believed.

Second, even if there is no dispute that certain scientific information failed to comport with applicable quality standards, EPA could choose not to "update the substance of the [risk] assessment" if it concluded that doing so would be too burdensome on Agency resources. Indeed, as time passed and a scientific data base became egregiously obsolete and erroneous the cost and burden of updating a demonstratively obsolete scientific data base would rise. The language EPA proposes could permit the Agency to argue that performing such an update required too many resources and would delay decisionmaking too long.

EPA's proposed language would require a sort of weighing of the benefits of improving information against the costs. However, the Agency proposes to compare benefits to the public against costs to the Agency. This approach is not consistent with either the law or OMB's implementing guidance. Surely, neither the Data Quality Act nor OMB's

implementing guidance intended such perverse outcomes, so these loopholes are clearly inconsistent with both law and OMB policy.

> *c. EPA proposes to apply this empty adaptation of the information quality language in the Safe Drinking Water Act to health risk assessments only, thereby denying the relevance of the language to safety and environmental risks.*
>
> In an effort to expand these guidelines to apply to environmental and safety-related risk assessments, the Agency intends to seek input from appropriate stakeholders and the scientific community [lines 680-682].

One of the most revealing provisions in EPA's proposed guidelines is its intention to limit the application of even this scaled-down version of the basic information quality standards of the Safe Drinking Water Act to human health risk assessments only. EPA produces a wide range of safety assessments, such as the derivation of Reference Doses and Reference Concentrations, which become integral parts of its wide-ranging regulatory programs. These safety assessments are regularly used by States and other co-regulators. They are used for writing various permits and establishing cleanup standards for the Agency's various site remediation programs. Indeed, there are few information disseminations EPA makes that are more influential.

Yet, EPA proposes to exempt its safety assessments from all information quality standards until an unspecified future date at which time an unknown set of standards might apply. Remarkably, the stated purpose of this delay is to confuse scientific data quality issues with the political and policy concerns that "appropriate stakeholders" would raise. It is hard to imagine a worse process for ensuring and maximizing the quality of scientific information related to safety risks.

EPA's proposal also would exempt environmental risk information from these basic quality standards. This is so remarkable a position for the Environmental Protection Agency to take that it sounds like self-parody. If EPA were to include this exemption in its final standard, the only reasonable conclusion to draw would be that no environmental risk information disseminated by EPA meets even basic information quality standards.

HOW EPA PROPOSES TO ENSURE AND MAXIMIZE THE QUALITY OF INFORMATION FROM EXTERNAL SOURCES (SECTION 3.5)

> *a. EPA provides little or no information concerning how it proposes to ensure and maximize information quality with respect to external information.*
>
> EPA recognizes that the State and other governments and third party information issue is complex and requires more thought and collaboration with States, the scientific and

> technical community and other external data providers. Consultation is needed to best ascertain and address how these guidelines may apply to external sources, and to ensure the guidelines are sufficiently flexible to encourage the appropriate use of external information while also ensuring and maximizing the quality of information EPA disseminates. Therefore, EPA is taking and will continue to take steps to ensure that the quality and transparency of data and information provided by external sources is sufficient for the intended use [lines 684-690].

It is difficult to discern from EPA's proposed information quality guidelines exactly what the Agency is proposing in this regard. EPA's proposed guidelines are egregiously deficient and the public has been denied a reasonable opportunity to comment.

OMB's government-wide guidelines make no distinction among the sources of information that agencies disseminate. Agencies are responsible for ensuring and maximizing the quality of information they disseminate irrespective of how they obtained it. Thus, any final guideline that EPA issues which make distinctions among sources would be procedurally flawed.

EPA's final guidelines cannot apply discriminatory procedures or quality standards based on the source of information upon which it relies. All information that EPA disseminates must meet applicable quality standards irrespective of its source. Consultation may be necessary to develop effective implementation procedures and oversight systems, but these needs do not transcend or nullify the Data Quality Act or OMB's government-wide guidelines.

Federal information quality standards may impose new burdens on States and other co-regulators to the extent that they historically have not satisfied the information quality standards that EPA itself claims to achieve. These burdens are not so great, however, that they justify the abandonment of reasonable standards for information quality. States and other co-regulators are welcome to apply whatever information quality standards they want in their own activities, but they must meet federal information quality standards to effectively perform their duties under federally authorized or delegated programs.

b. EPA proposes to indefinitely postpone the development of information quality guidelines with respect to data obtained from outside sources.

> For information that is either voluntarily submitted to EPA in hopes of influencing a decision or that EPA obtains for use in developing a policy or regulatory decision, EPA plans to work with States and other governments, the scientific and technical community and other interested data providers to develop and publish factors that EPA would use to assess the quality of this type of information provided by external sources and used by EPA for specific purposes [lines 691-695].

Frankly, it is baffling why EPA appears to be confused about what to do in this regard. External information, whether voluntarily submitted or obtained by EPA, ought to meet the same standards that apply to any other information that the Agency disseminates if it is intended to influence EPA decisionmaking. Categorical distinctions based on source rather than quality attributes would be quite obviously discriminatory. Where external information is superior in quality to information gathered by an agency, the external information should supplant the agency's own data.

It is worrisome that EPA appears to be leaning toward a two-tiered regime in which information submitted voluntarily by outside parties might face more severe burdens than information gathered directly by EPA or by its contractors and grantees. The Data Quality Act does not authorize EPA to engage in such discrimination on grounds unrelated to information quality, and OMB's government-wide guidelines do not provide any latitude for discriminatory treatment.

EPA should reverse direction on this matter and provide explicit incentives for outside parties to generate and voluntarily provide information that meets appropriate information quality standards if possible. In particular, EPA should state clearly that it will always rely upon information submitted voluntarily that is superior in quality to what the Agency currently possesses and otherwise would disseminate or use – even if this external information does not fully satisfy desired information quality standards. Such an approach would benefit the public by improving the quality of information and stimulate the genius and productive use of resources well beyond those within EPA.

EPA'S PROPOSED MECHANISM FOR PRE-DISSEMINATION REVIEW (SECTION 4.1)

Pre-dissemination review is arguably the most critical element of OMB's government-wide guidelines. An effective pre-dissemination review procedure would reduce, and in principle could eliminate, the host of concerns, problems and controversies associated with post-dissemination challenges and correction procedures. Unfortunately, EPA's proposed guidelines contain essentially no content on this vital matter:

> Each EPA office and region will incorporate the information quality principles outlined in these guidelines into their existing pre-dissemination review procedures as appropriate. Offices and regions may develop unique and new procedures, as needed, to provide additional assurance that the information disseminated by or on behalf of their organizations is consistent with these guidelines [lines 698-701].

Without guidance to EPA offices and regions, there is absolutely no chance that the Agency's information quality principles will be incorporated into "existing pre-dissemination review procedures." The identity of these procedures is not revealed, and the fact that they need only do so "as appropriate" merely underscores the fundamental emptiness of this

commitment. As if this approach were not assured of ineffectiveness, offices and regions may develop "unique and new procedures," but only "as needed." Apparently, EPA sees the need to craft a redundantly ineffective system for pre-dissemination review.

EPA should establish a goal of zero non-frivolous post-dissemination challenges. As indicated in the following section, no post-dissemination corrections procedure can be fully effective in avoiding the social costs of disseminating information that fails to satisfy appropriate information quality standards. Errors that lead to non-frivolous post-dissemination challenges undermine public confidence in EPA and its mission credibility. A pattern of errors is likely to be interpreted as evidence of arbitrary and capricious conduct

Therefore, EPA should apply a principle of precaution to its dissemination of information. Striving to achieve the goal of zero post-dissemination challenges requires the development of rigorous, transparent, objective and credible pre-dissemination review procedures. EPA can prevent these procedures from causing undue delay by fully integrating them into its development of information products.

One way EPA could infuse among its program and regional offices a high regard for information quality is to require them to document their compliance with supporting statements and research protocols when they use or disseminate information obtained from approved information collection requests. Evidence of material noncompliance is likely to be *prima facie* evidence that information does not meet applicable information quality standards. A system of compliance assurance would inculcate the values EPA officials say they are committed to achieving.

Of course, this also would provide a useful device for weeding out instances in which the Agency uses or disseminates information that was subject to the Paperwork Reduction Act but lacks an approved OMB control number. Further, EPA officials could categorically reject the use of common evasive techniques, such as securing responses from nine or fewer persons in order to avoid having to obtain OMB approval. In short, the existing paperwork review process provides an excellent management tool for achieving information quality goals. It is somewhat surprising that EPA did not identify it in its list of existing management systems, especially since the Data Quality Act amended the Paperwork Reduction Act – the very authority under which OMB reviews information collection requests.

EPA'S PROPOSED ADMINISTRATIVE MECHANISM FOR CORRECTING ERRONEOUS INFORMATION (SECTIONS 5.1-5.3)

Developing an effective system for correcting errors is a very challenging exercise. Any agency is inherently conflicted when it has the authority to review and pass judgment on

the merits of its own decisions. Only a fully external and independent system has the capacity to overcome these conflicts. OMB has given agencies the discretion to craft internal error correction mechanisms, but that latitude should not be misconstrued as a lack of concern about the perils of self-oversight.

a. EPA proposes to largely delegate the errors corrections process to those with the greatest conflicts of interest (section 5.1).

EPA's approach fundamentally misses the mark. Instead of crafting a post-dissemination review process that mimics, to the maximum extent practical, what an independent and external review process might do, EPA has proposed a process that is rife with conflicts of interest:

> OEI manages the administrative mechanisms which enable affected persons to seek and obtain, where appropriate, correction of information maintained or disseminated by the Agency that does not comply with EPA or OMB Information Quality Guidelines. Working with the program offices, regions, labs and field offices, OEI will receive complaints (or copies) and distribute them to the appropriate EPA information owners. "Information owners" are the responsible persons designated by management in the applicable EPA program, or those who have responsibility for the quality, objectivity, utility and integrity of the information product or data disseminated by EPA [lines 705-711].

The Office of Environmental Information is arguably the least conflicted of all EPA offices inasmuch as it is a staff office to the Administrator and has no substantive environmental policy responsibilities. But, EPA proposes that OEI act as a mere clearinghouse for receiving and processing complaints. The real job of managing corrections would be left to "information owners" -- the very personnel whose information disseminations are under challenge!

It is possible that "information owners" could be held accountable for the "the quality, objectivity, utility and integrity of the information product or data disseminated by EPA," but accountability has long been a weak link in the federal bureaucracy. "Responsible persons designated by management" are not quite as accountable as, say, "responsible parties" in a Superfund action. Indeed, civil service protections essentially prevent an agency from holding individuals accountable for poor performance. Therefore, while it is possible that EPA could craft an administrative mechanism that worked as proposed, it would be virtually impossible to accomplish even if EPA left no stone unturned to achieve it. That EPA discloses no plan for achieving individual accountability merely confirms that the Agency's proposed administrative mechanism cannot work.

This is not to say that "information owners" will resist and reject all complaints. Quite to the contrary, they can be expected to respond promptly and affirmatively insofar as

they agree with a complaint. Generally, "information owners" and program offices can be expected to agree when corrections serve to reinforce their policy preferences, and to disagree otherwise. That makes EPA's proposed error correction process systematically and irrevocably biased. Such a system does not comply with OMB's "intent … to ensure that agency guidelines specify an objective administrative appeal process" (67 FR 8458, emphasis added).

If EPA finalizes a review process in which conflicted Agency offices have primary responsibility for making initial correction determinations, then it also must include a very low hurdle for appeals to a genuinely "objective administrative appeals process." Further, the appeals process must be capable of acting on appeals on any grounds and have no discretion to refuse to hear an appeal. Appeals may be based on any number of arguments ranging from a failure to take any action to a rejection of a challenge to a failure to make timely corrections after agreeing with a challenge. An appeal must be permitted even if the complainant prevails at the initial hearing. Otherwise, a complainant may face a situation in which a program office agrees that disseminated information does not meet applicable information quality standards but then replaces it with other information that also fails to meet the applicable standard. It would be unfair to compel a complainant to endure a merry-go-round in which it must repeatedly file complaints to correct erroneous information disseminated to correct other erroneous information.

b. EPA's proposed rules for standing to request a correction of information from the Agency appear appropriately unrestrictive (section 5.2)

> Any individual or person may request a correction of information from EPA, if that individual or person is an "affected person". For the purposes of these guidelines, "affected persons" are persons who may benefit or be harmed by the disseminated information [lines 714-716].

EPA appears to have tracked OMB's definitions closely and should be commended. EPA has used an expansive definition of "person" elsewhere in its proposed guidelines in a section exempting a huge category of information from information quality guidelines. Therefore, the public has reason to be concerned whether the definition of "affected person" is in fact as broad as it appears. EPA should clarify this matter by explicitly stating what entities do not qualify as affected persons so that the public can verify that the apparent interpretation is correct.

c. EPA needs a process for accepting and considering anonymous complaints (section 5.2).

EPA also needs to establish a procedure whereby information can be challenged anonymously. Many persons who have an interest in correcting erroneous information fear

that the Agency might take retaliatory action against them if they complain. In some cases this could be a regulated party who is concerned that complaining could endanger its relations in its future dealings with EPA. It is easy to dismiss such concerns as unfounded, but the mere perception that they could be true is enough to stifle complaints.

In other cases it might not be a regulated party who needs protection, but a researcher or scientist who fears retribution. For example, a scientist who learns that certain information submitted to EPA does not in fact meet applicable information quality standards could well refrain from providing this information. Of course, a reasonable nexus between the nature of the information and the particularized concern for retribution ought to be necessary to take advantage of this process. Otherwise, the complaint process could be overrun by malicious complaints motivated by envy, jealously or perhaps competitive rivalry.

PROBLEMS WITH THE KINDS OF CORRECTION REQUESTS EPA WILL NOT CONSIDER (SECTION 5.4)

EPA's proposed guidelines depart from OMB's government-wide guidelines in numerous ways.

a. EPA proposes to improperly expand the domain of complaints that it will not consider.

At the same time that EPA seems to proposing easy access to its corrections process, it also appears to be proposing to greatly expand the domain of complaints that it will not consider. At the top of this list are complaints that have other unspecified defects besides frivolity:

> EPA will review every request for correction under these guidelines and consider it for correction unless:
>
> - The request itself is deemed "frivolous," including those made in bad faith or without justification, deemed inconsequential or trivial, and for which a response would be duplicative of existing processes, unnecessary, or unduly burdensome on the Agency [lines 730-734, emphasis added].

The basis for this proposal is two passing references in the preamble to OMB's government-wide guidelines:

> "Agencies, in making their determination of whether or not to correct information, may reject claims made in bad faith or without justification, and are required to undertake only the degree of correction that they conclude is appropriate for the nature and timeliness of the information involved, and explain such practices in their annual fiscal year reports to OMB.

> …
>
> Overall, OMB does not envision administrative mechanisms that would burden agencies with frivolous claims. Instead, the correction process should serve to address the genuine and valid needs of the agency and its constituents without disrupting agency processes. (67 FR 8458, emphasis added).

Nothing in this language authorizes EPA to craft a host of categories of complaints that it can simply ignore. EPA would expand the domain of "frivolous" complaints to include those which, in its sole judgment, it "deems" "inconsequential or trivial." Presumably, these are additional attributes not already implied by mere frivolity, but the public is hard-pressed to know exactly what they might be.

Particularly worrisome is EPA's proposed wholesale rejection of complaints "for which a response would be duplicative of existing processes, unnecessary, or unduly burdensome on the Agency." Whether EPA has an "existing process" says nothing about the effectiveness of that process in resolving information quality issues. Indeed, because EPA is so rich with administrative processes that the public can hardly keep track of, much less master, them all, it is possible that EPA could reject almost all complaints it receives on the ground that the complainant has failed to avail himself of one or another "existing process." The situations in which a response could be deemed "unnecessary" or "unduly burdensome on the Agency" are limited only by one's imagination.

Interestingly, what is missing from each of these categories of complaints that EPA proposes to ignore is any consideration of whether the complaint has merit. The best inference one can draw from this is that EPA expects a flood of legitimate complaints and has become obsessed with containing the workload of making corrections. EPA has not proposed to directly ration access to its error correction process – say, to the first *N* complaints received per year – but the restrictions it has proposed appear to have much the same effect.

> *b. EPA improperly proposes to deny access to its error correction process on to any complaint about information contained in rulemaking.*
>
> EPA will review every request for correction under these guidelines and consider it for correction unless:
>
> …
>
> - It pertains to EPA actions, where a mechanism by which to submit comments to the Agency is already provided. For example, EPA rulemakings include a comprehensive public comment process and impose a legal obligation on EPA to respond to comments on all aspects of the action. These procedural safeguards assure a thorough

> response to comments on quality of information. EPA believes that the thorough consideration required by this process meets the needs of the request for correction of information process. A separate process for information that is already subject to such a public comment process would be duplicative, burdensome, and disruptive to the orderly conduct of the action [lines 730-731, 737-745].

This category of complaints EPA proposes to ignore is especially brazen, and there is a good chance that it could backfire. The public comment process of the Administrative Procedure Act was never designed to achieve information quality objectives. Indeed, EPA actions subject to judicial review under the APA withstand judicial scrutiny merely if a reviewing court concludes that they are not arbitrary and capricious. In its proposed guidelines, EPA does not point to any APA provision or case law which the public can rely upon as precedent indicating that courts are attuned to information quality objectives and are committed to seeing that they are achieved.

Of course, the courts might welcome such an opportunity. Courts now give great deference to agency expertise, including a broad implicit presumption that the information agencies rely upon meets intuitively reasonable quality standards. If EPA exempts information disseminations from its corrections process in cases where courts have review jurisdiction, courts might decide to withdraw this deference and take seriously plaintiffs' claims that an agency action was based on materially flawed information. EPA guidelines that exempt such information from the normal error correction process would invite courts to use APA proceedings make these determinations.

For some affected persons, this could be an important (though partial) remedy. APA standing requirements are presumably more restrictive than what would be required to petition EPA for review under its internal error correction procedure. Further, APA proceedings would probably be much more expensive to pursue, thus making APA review attractive only for very significant information quality disputes. Finally, if courts were inclined to hear information quality complaints they would likely limit their attention to allegations of material error. Therefore, the majority of information quality disputes contained in regulatory actions subject to APA review would not be covered. The danger to EPA is that it cannot foresee the depth and breadth of judicial review that it would be inviting, and administrative agencies generally prefer to avoid creating new legal uncertainties.

An additional problem would arise with respect to information contained in proposed rulemakings, which are not considered final agency actions under the APA. Affected persons may believe that they are seriously harmed by erroneous information contained in these actions, and the harm they experience would persist unless and until EPA responded to public comment and promulgated a final action that corrected these errors.

This could, and often does, take years to complete. Sometimes, EPA never takes final action at all. On the theory that the damages caused by erroneous information occur immediately and persist indefinitely upon proposal even if regulatory requirements do not, a case can be made that a proposed rule would constitute final agency action for purposes of information quality only. If EPA denies affected persons access to its error correction process, then the Agency invites the courts to accept APA review of a proposed rule on the ground that information quality issues are in fact ripe.

c. EPA proposes to limit its consideration of complaints to the time period allotted for public comment.

> If EPA cannot respond to a complaint in the response to comments for the action (for example, because the complaint is submitted too late to be considered along with other comments or because the complaint is not germane to the action), EPA will consider whether a separate response to the complaint is appropriate. EPA may consider frivolous any complaint which could have been submitted as a timely comment in the rulemaking or other action but was submitted after the comment period [lines 746-751, emphasis added].

For the reasons outlined above, EPA's proposal to procedurally reject complaints arising from rulemaking actions suffers from transparently erroneous reasoning. The Agency proposes to compound this error by asserting the authority to respond only to those complaints included in public comments submitted during the applicable public comment period. EPA lacks any authority under the Data Quality Act to do this. Moreover, nothing in OMB's government-wide guidance remotely suggests that OMB intended to give agencies' the discretion to craft highly exclusionary, punitive procedures. Indeed, OMB has clearly stated that there is no "statute of limitations" for complaints:

> The agency's pre-dissemination review, under paragraph III.2, shall apply to information that the agency first disseminates on or after October 1, 2002. The agency's administrative mechanisms, under paragraph III.3., shall apply to information that the agency disseminates on or after October 1, 2002, regardless of when the agency first disseminated the information (§III.4, emphasis added).

Under EPA's reasoning, virtually any complaint received outside of public comment could be rejected as frivolous, for it seems entirely logical that almost all such complaints could have been submitted during that period. Moreover, EPA's approach presumably would require the Agency to reject any complaint that could have been submitted during a previous public comment period. This scheme permits information contained in rulemakings to be challenged once and only once in some cases (and not at all in others). How this scheme could possibly be consistent with the letter or spirit of the Data Quality Act EPA does not explain.

A special problem arises when information that is disseminated as part of a rulemaking action affects persons whose only interest in the rulemaking action is the information the Agency disseminated. EPA's approach would compel them to behave as if they are regulated parties. This is clearly a nonsensical result and it imposes an undue burden on affected persons.

EPA's scheme also creates the likelihood that some complaints about information contained in rulemakings might never be subject to challenge under any circumstances. For example, if EPA concluded that "the complaint is not germane to the action," then the Agency would have no obligation to respond to the complaint either in a response to comments document or in a corrections action. EPA also proposes to reserve additional discretion to decide "whether a separate response to the complaint is appropriate." EPA provides no corrections mechanism at all for complaints it rejects for a germaneness defect and concludes that a separate response was not appropriate.

PROBLEMS WITH EPA'S PROPOSED MECHANISM FOR RESPONDING TO REQUESTS FOR CORRECTION (SECTION 5.5)

EPA's procedures for responding to those complaints it alone judges worthy need considerable elaboration and refinement. The Agency's proposed guidelines contain no criteria for evaluating complaints; no deadlines for making decisions or correcting information determined to be erroneous; and unfettered discretion to deny relief in any and all cases it determines to be valid.

> If a request for correction of information is deemed appropriate for consideration, EPA will make a decision on the request on the basis of the information in question. If a request is approved, EPA will take corrective action. Whether a request is approved or not, EPA will send an explanation to the requester. EPA may elect not to correct some completed information products on a case-by-case basis due to Agency priorities, time constraints, or resources. OEI will submit reports to OMB on an annual basis beginning January 1, 2004 regarding the number, nature and resolution of complaints received by EPA [lines 758-764, emphasis added].

a. EPA's proposed domain for corrections does not include matters related to its interpretation of the guidelines.

EPA's error correction process focuses on actual disseminations of (covered) information. Elsewhere EPA has reserved to itself substantial (and in some cases, unbridled) discretion to make new categorical and case-by-case applicability decisions. This means that EPA is likely to reject some complaints on the procedural ground that the information challenged is not covered by the guidelines. EPA's proposed error correction process contains no procedure for the appeal of such procedural denials.

b. EPA proposes no criteria for decisionmaking on the merits of complaints it deems "appropriate for consideration."

Under EPA's proposed corrections process, affected persons have no clue what criteria the Agency would use to evaluate complaints. To say that "EPA will make a decision on the request on the basis of the information in question" adds no clarity whatsoever. Based on EPA's proposed guidelines *in toto*, a reasonable inference is that EPA intends to make case-by-case determinations based on criteria that it chooses *ex post* and *ad hoc*. This approach lacks the systematic predictability that corrections mechanisms must have to be effective. It also lacks any hint of objectivity, a required attribute under OMB's government-wide guidelines.

c. EPA proposes no deadlines for making decisions on the merits of complaints it deems "appropriate for consideration."

Deadlines for action are essential for any administrative mechanism to be credible. A promise to "make a decision" is empty if it lacks a deadline and some form of due process.

EPA should establish clear and reasonable deadlines for making decisions on the merits of complaints. Further, as evidence of good faith, EPA should clearly suffer a penalty in any instance where it fails to meet these deadlines. For example, EPA could automatically grant any and all documented complaints that it cannot process in a timely manner. A desire to avoid these default judgments would provide a delightful incentive for EPA to establish and follow effective pre-dissemination review procedures.

d. EPA proposes no deadlines for actually making corrections of any information it agrees is erroneous or does not meet applicable information quality standards.

Securing EPA's agreement that information it has disseminated fails to meet appropriate information quality standards is but half of an effective corrections process. EPA also needs procedures to ensure that corrections are made once errors are discovered. EPA's proposed corrections process lacks any such process for ensuring that corrections are made.

At a minimum, EPA needs to immediately withdraw erroneous information from dissemination without worrying about how to replace it. Once a complaint has been determined to be meritorious, complainants can be asked (and would most likely be quite willing) to help the Agency identify and report additional instances in which the same error appears. Complainants also could assist in identifying secondary information derived from erroneous primary data.

e. EPA improperly proposes to reserve to itself unfettered discretion to decide that "Agency priorities, time constraints, or resources" trump meritorious complaints.

> EPA may elect not to correct some completed information products on a case-by-case basis due to Agency priorities, time constraints, or resources [lines 761-762].

This sentence is one of the most amazing in the entire text of EPA's proposed guidelines. It is hard to interpret as anything other than a stunningly brazen display of bad faith. EPA seems to believe that the Data Quality Act directs agencies to improve information quality only when they feel like doing so, and that OMB was only kidding when it issued government-wide implementing guidelines. Should EPA finalize any language remotely similar to this, it will only invite a flood of lawsuits asking courts to reject its guidelines and to impose on it the strictest possible application of OMB's government-wide guidelines.

f. EPA proposes a process that does not meet OMB's standard for objectivity.

The process EPA proposes has little or no objectivity. Agency "information owners" – those staff members most likely to be conflicted in reviewing complaints – would have the initial responsibility. Next in line would be the political official under whose employ the "information owner" works. Neither of these elements is at all objective.

The final review process consists of an executive panel headed by the Chief Information Officer and composed of other political officials. Such a panel has the barest façade of objectivity, and even this is ephemeral because the panel's role would be purely advisory.

EPA needs to reconsider its entire approach to the corrections mechanism and take more seriously OMB's instruction that the process be objective:

> An objective process will ensure that the office that originally disseminates the information does not have responsibility for both the initial response and resolution of a disagreement (67 FR 8458).

No internal agency process can be truly objective. Still, EPA can do much better than craft a process that has no objectivity at all. For a start, EPA should consider empowering its Chief Information Officer to make these determinations. The CIO is the least conflicted of all EPA political officials, subject to the authority of the administrator, serves at the pleasure of the president, and can be held accountable by Congress.

RESPONSES TO SPECIFIC EPA REQUESTS FOR COMMENT

In addition to seeking comment on the proposed guidelines generally, EPA has requested comment on specific issues. This section reiterates some of the comments above in the format EPA prefers and adds additional remarks where appropriate.

a. Influential Information

1. "Is this an appropriate approach?"

As indicated above, EPA's approach to establishing and implementing quality standards for influential information is inconsistent with both the Data Quality Act and OMB's government-wide guidelines. In particular:

- EPA's proposed use of categorical information quality standards improperly ignores informational content. Categories are poor proxies for content. The content of information EPA disseminates should determine the applicable quality standard, not the form in which dissemination occurs. The Data Quality Act was passed in part as a response to concerns that agencies were disseminating influential information through various "backdoor" channels. An information quality guideline that ratifies this practice cannot be consistent with law.

- EPA's proposed definition of "top Agency actions" is vague and impossible to monitor externally. Based on the limited information provided, the public has no clue where EPA intends to draw the line discriminating "top" Agency actions from all others. Because EPA does not define the term "action," a huge swath of information disseminations could be exempt.

- EPA's proposed inclusion of "economically significant" regulatory actions implicitly and inappropriately excludes "significant" regulatory actions. Economically significant regulatory actions certainly ought to be covered. EPA implies, however, that merely "significant" regulatory actions would be exempt. Any regulatory action that warrants OMB review ought to be considered presumptively influential. The applicable quality standard can be lowered upon a persuasive demonstration that the "dissemination of the information will [not] have or does

[not] have a clear and substantial impact on important public policies or important private sector decisions (§V.9, 67 FR 8460)."

- EPA's proposed inclusion of "work products undergoing peer review" implicitly and inappropriately excludes from the domain "influential" scientific and technical information that does not undergo peer review. Such work products certainly ought to be considered influential. EPA implies, however, that work products which it does not subject to peer review would not be considered influential. EPA is entitled to make management decisions concerning how to allocate scarce resources on peer review. However, internal management discretion should not and cannot be used as a device for deciding whether information is influential.

- EPA's proposal to make case-by-case determinations that disseminations contain "influential" information lacks a transparent and effective mechanism for making these determinations, and the criteria necessary to implement one. Case-by-case determinations are made necessary by EPA's categorical approach, but EPA has failed to provide a transparent regime for making these decisions. EPA's proposed guidelines disclose no procedures, no criteria, and no appeal mechanism – all of which are essential for case-by-case determinations to be credible.

2. "Is the scope of information too broad?"

As indicated above, EPA's approach to establishing and implementing quality standards for influential information is inconsistent with both the Data Quality Act and OMB's government-wide guidelines. Indeed, the very way EPA has posed this question telegraphs a fundamental error. Though EPA is concerned that it may have defined the scope of influential information too broadly, EPA has clearly crafted it too narrowly. Huge swaths of information that EPA disseminates which "will have or does have a clear and substantial impact on important public policies or important private sector decisions" (§V.9, 67 FR 8460) would be improperly excluded from the Agency's proposed definition.

This defect is attributable to a potent combination of ill-advised provisions. First, EPA relies on a categorical rather than content-based approach to determine what information disseminations are covered, and which of these are influential. Second, EPA proposes a case-by-case determination regime that, as noted above, has no transparent

mechanism, no criteria, and no appeal procedure. Third, and perhaps most importantly, EPA proposes defaults that bias its guidelines toward the exclusion of information from being classified as influential. If categories and defaults and *ad hoc* procedures are going to be used, then EPA should state that the default assumption is that information is influential pending a persuasive showing that it is not.

3. "Are there other classes of information that should be included?"

As indicated above, EPA should abandon its categorical approach to determining whether information is influential. The content of information disseminated should determine the applicable quality standard, not the form in which it is distributed.

If EPA insists on using categories, then the default state should be that information is presumptively influential pending a persuasive showing by the Agency that it is not.

4. "EPA intends to develop experience implementing its definition of influential information over the first year, and then potentially broaden it to incorporate other classes of information disseminated by EPA. Is this an appropriate approach and consistent with the goal to continually improve Agency information?"

No. EPA's proposal imparts a systematic bias against compliance with the Data Quality Act and conformity with OMB's government-wide information quality guidelines. EPA may well be genuinely concerned that the burden of meeting these new standards could be substantial. If that is so, however, then EPA ought to be more humble and less self-congratulatory in its claims about the effectiveness of its existing internal management systems in achieving information quality objectives.

An unenforceable promise to "potentially broaden" the Agency's definition of influential information sometime in the future has absolutely no value. EPA cannot reasonably expect the public to give EPA the benefit of the doubt given the extraordinary effort the Agency has taken in its proposed guidelines to evade the law and impede OMB in its efforts to ensure government-wide compliance.

EPA's obligation is to comply with the law and OMB's government-wide guidelines. If OMB's guidelines prove unworkable despite a conscientious effort to comply, then OMB can be persuaded to modify them. If OMB's hands are tied because the Data Quality Act denies EPA necessary and appropriate flexibility, then EPA should ask Congress to modify the law.

b. Reproducibility

1. "What comments do you have on the Agency's approach to facilitating the reproducibility of influential information?"

EPA's approach to ensuring reproducibility fails to satisfy any conceivable minimum standard. In particular:

- EPA lacks a reasoned application of OMB's reproducibility requirement to original and supporting data. How EPA would implement this requirement cannot be clearly divined from the Agency's proposal. Hence, EPA has left public commenters in the dark and denied them a reasonable opportunity to respond.

- EPA proposes to limit the high quality standard applicable to "influential" information to only those cases where it is achieved. According to EPA's proposal, the Agency intends to rely exclusively on existing internal management systems to assure information quality. But, EPA merely asserts that these systems achieve appropriate information quality standards and provides no supporting data or analysis. This reasoning is inherently circular and therefore unacceptable.

- EPA improperly proposes to assert that information it disseminates satisfies the high quality standard applicable to "influential" information even if underlying components do not. EPA's guidance presumes the existence of an information quality "magic wand" that can be waved over data that does not meet applicable information quality standards so as to bless information products derived from these data. The quality of a derivative information product cannot be greater than the quality of its inputs.

2. "Is [the Agency's approach to facilitating the reproducibility of influential information] appropriate for the influential scientific, financial, and statistical information EPA disseminates?"

No. EPA's approach does not ensure that information meets basic quality standards. Therefore, it is impossible for this approach to satisfy the higher standard that applies to influential scientific, financial, and statistical information.

There are other defects in EPA's proposed approach when applied to influential information. In particular:

- EPA proposes to substitute transparency for quality in its higher standard for "influential" information. EPA appears to suggest that full disclosure is all that is required to achieve the higher standard appropriate for influential information. This is incorrect. Transparency is a necessary condition for reproducibility, and reproducibility is but necessary condition for independent parties to be able to discern whether influential information meets the statutory test of objectivity. Neither transparency nor reproducibility ensure or maximize information quality. Rather, they merely permit departures from applicable quality standards to be detected.

3. "What types of original and supporting data do you believe should or should not be subject to a reproducibility requirement given ethical, feasibility, or confidentiality constraints?"

EPA's proposed guidelines fail to provide adequate information concerning the extent to which it intends to subject original and supporting data to a reproducibility requirement. In particular:

- EPA provides little or no information concerning how it proposes to ensure and maximize information quality with respect to external information. EPA's proposal lacks a proposal. The public has nothing on which to comment.

- EPA proposes to indefinitely postpone the development of information quality guidelines with respect to third-party data. EPA's proposal merely punts this issue to an undetermined future date. The public has nothing on which to comment.

4. "What suggestions do you have for performing and reporting robustness checks of influential analytic results in cases where public access to data and methods will not occur due to other compelling interests such as privacy, trade secrets, intellectual property, and other confidentiality protections?"

EPA was supposed to disclose in its proposed guidance a plan for performing and documenting robustness checks in situations where transparency was not possible for

"compelling reasons." The Agency's request for suggestions is fine, but it is not a substitute for a proposal on which to comment.

Nevertheless, certain elements of what little EPA says about robustness checks deserve attention. In particular:

- EPA proposes to evade compliance with OMB's requirement for robustness checks in cases where transparency is not feasible. EPA proposes to require robustness checks only "to the extent practicable." OMB requires "especially rigorous" robustness checks, not merely those that are convenient, and these checks must be documented.

5. "In particular, how might such robustness checks be applied to third party data that are used in analyses included in influential scientific, financial, and statistical information disseminated by EPA?"

In cases where transparency is impossible for "compelling reasons," EPA should apply the same robustness checks irrespective of source. There is no legitimate basis for discriminating. It is possible that EPA will have less information about the quality of information it obtains from outside parties, and it is fully appropriate that greater care might be necessary to ensure that information from outside sources meets appropriate information quality standards. Nevertheless, this is fundamentally different from imposing a higher standard on information from outside sources. Information that cannot be reproduced, irrespective of its source, deserves the same level of scrutiny via robustness checks.

c. *Influential Risk Assessment*

1. "What suggestions do you have with respect to the EPA adaptation of the SDWA principles for influential scientific risk assessments regarding human health risks?"

EPA's adaptation of the SDWA principles is deeply and fatally flawed. Instead of adopting the basic information quality standards set forth in the Safe Drinking Water Act, EPA proposes to "adapt" this language in ways that drain it of content. In particular:

- EPA proposes to evade the statutory language of the Safe Drinking Water Act for risk-related information. The SDWA language is directive and sets forth nondiscretionary duties for the use of best available science and information collected using

best or appropriate methods. EPA's proposed adaptation would make this language merely advisory

- EPA proposes to transform the information quality language in the Safe Drinking Water Act so as to authorize the use of demonstrably inferior scientific and technical information. EPA proposes to stop the clock on science at any point it chooses and reject all scientific advancements that subsequently arise, if it so chooses This implicitly authorizes EPA to avoid learning and to disseminate demonstrably inferior (or even grossly incorrect) scientific and technical information.

- EPA proposes to apply this empty adaptation of the information quality language in the Safe Drinking Water Act to health risk assessments only, thereby denying the relevance of the language to safety and environmental risks. Quite remarkably, the Environmental Protection Agency implies that information it disseminates regarding environmental risk cannot meet these basic information quality standards.

2. "Do you think that an adaptation of the SDWA quality principles is appropriate for most influential scientific risk assessments regarding human health risks disseminated by EPA?"

No. EPA should adopt the SDWA information quality principles as its default policy and apply a clearly defined and articulated case-by-case process for identifying instances in which these principles ought not to apply. A high hurdle ought to be established to justify departures from this basic information quality standard.

d. Sources of Information Disseminated by EPA

EPA specifically requests comment on what quality standards ought to apply to information that it obtains from outside parties and subsequently disseminates. Unfortunately, EPA begins from a potentially incorrect premise:

> "Although this information may not be covered by these guidelines when it is first generated by outside sources, it may be covered by the guidelines if the Agency subsequently decided to use the information in a publication or policy decision" (page 26, emphasis added).

In general, information obtained from outside parties is covered if EPA subsequently disseminates it. EPA's statement thus may be correct, but might not be depending on how permissive the Agency intends it to be. Coverage exclusions have been well stated by OMB

and do not include outside information *per se*. Significant defects in EPA's approach to scope and coverage issues have been discussed above.

1. "EPA would like you to suggest specific assessment factors that the Agency should consider using when assessing specific kinds of information submitted to EPA by outside sources, or information EPA obtains from outside sources."

Appropriate quality standards apply to any covered information that EPA disseminates irrespective of its source. In addition, the same quality standards should apply irrespective of source. EPA cannot legitimately impose a higher quality standard on information it receives from outside parties than it requires of information that it self-generates or obtains from outside parties on its own effort. Similarly, EPA cannot authoritatively disseminate or use information that it obtains from outside parties where that information meets a lower quality standard than information already within its possession or otherwise available. In addition to this general rule of neutrality with respect to source, EPA must use transparent and effective disclaimers when it disseminates information for which it does not intend for users to impute Agency sponsorship, support or endorsement.

EPA needs to strictly enforce contractual obligations with its grantees, cooperators and contractors to ensure that data they generate are fully disclosed so as to enable reproducibility. Full disclosure is essential for reproducibility, and exceptions from full disclosure should be kept to a bare minimum. Privacy concerns, for example, can be solved by stripping personal identifying information from a data set.

EPA should not contract with any party who insists on retaining proprietary intellectual property rights in research methods, data, models or analyses produced in fulfillment of a government contract. Serious consideration ought to be given to debarring researchers who refuse to fulfill these contractual obligations.

EPA also needs to establish a policy default disfavoring the use of proprietary research methods, data and models. Clearly, EPA ought not to be in the business of establishing and protecting a contractor from disclosure requirements, especially those that are intended to enable outside parties to evaluate its work. On the other hand, there will be cases in which proprietary models already have such widespread acceptance that reliance upon them actually enhances public confidence in information quality. For example, it makes much more sense for EPA to evaluate firms' financial capacities based on the ratings prepared by independent ratings firms rather than try to reinvent a new rating scheme just to ensure that it is reproducible.

EPA appears to be suggesting that it might use its guidelines to impose information quality standards on regulated parties who provide information to the Agency under the authority of law or regulation. This would be inappropriate. Quality concerns related to mandatory information collections can and should be fully addressed through existing OMB procedures for the centralized review and public comment on agency information collection requests submitted pursuant to the Paperwork Reduction Act.

2. "EPA also requests your input on how it should properly consult with the scientific and technical community in establishing these assessment factors."

EPA should consult broadly and widely with recognized scientific and technical experts and their professional societies. However, there is no single consultation model that appears likely to fit all cases. That said, scientific and technical experts will have inherent and severe conflicts of interest and lack expertise in relevant information quality issues. Severe conflicts of interest will arise on matters related to reproducibility, for example. Although full disclosure of research methods, data, models and results is generally expected in science, many scientists refuse to fully disclose this information to protect what they perceive as intellectual property rights. To the extent these scientists were funded by the federal government, any such rights are constrained by contract and the public has a legal right to obtain access. These limited property rights cannot be construed as a "compelling interest" that trumps transparency. For data quality purposes, however, what matters is that scientific information that cannot be reproduced will generally not meet the quality standard for influential information unless it can be reproduced.

e. Complaint Resolution

EPA seeks comments on its complaint resolution procedure, but hasn't provided enough information to enable informed public comment. Those elements EPA has disclosed are generally worrisome. In particular:

- EPA's proposed domain for corrections does not include matters related to its interpretation of the guidelines. EPA does not make clear whether or how an affected party can petition for review of an Agency decision denying the applicability of information quality guidelines. This is a critical defect. EPA's complaint resolution process is empty if complaints can be dismissed for procedural reasons.

- EPA proposes no criteria for decision making on the merits of complaints it deems "appropriate for consideration." This is yet another loophole that EPA proposes to provide itself. Again,

EPA cannot credibly claim that it has an effective complaint mechanism if is has the discretion to decide that certain complaints are not "appropriate for consideration."

- EPA proposes no deadlines for making decisions on the merits of complaints it deems "appropriate for consideration." Deadlines are essential for any process to be credible. What time periods are appropriate depend on how the process is constructed. The process EPA has proposed will be ineffective irrespective of what time periods might be included.

- EPA proposes no deadlines for actually making corrections of any information it agrees is erroneous or does not meet applicable information quality standards. Securing EPA's agreement that information it has disseminated warrants correction has no value unless the Agency actually takes action, and does so promptly.

- EPA proposes to reserve to itself unfettered discretion to decide that "Agency priorities, time constraints, or resources" trump meritorious complaints. This loophole would provide EPA the discretion to do nothing in response to all legitimate complaints. A credible process must create nondiscretionary duties to take action.

1. "Specifically, what suggestions do you have regarding the receipt of the initial complaint through the Office of Environmental Information?"

EPA proposes that the Office of Environmental Information serve little more than a clerical function. This is a prescription for failure. Among EPA offices, OEI is the least subject to conflicts of interest that undermine the objectivity which OMB requires. EPA should reconfigure the complaint resolution process so that OEI not only receives initial complaints but also is responsible for acting upon them.

To achieve this OEI needs access to recognized experts who are independent of the Agency and the "information owner" program office in particular. Therefore, OEI needs the authority to consult with outside experts on information quality matters. To be credible, this consultative process will need to be highly transparent yet restricted to information quality matters and kept away from substantive policy issues.

2. "Do you think a central point of entry is useful or problematic?"

A central point of entry makes sense, and it should be combined with an online system for timely public disclosure (except anonymous ones; see comments above). This is especially important in an agency like EPA where multiple offices may be using or disseminating the same information. It makes no sense to require affected persons to petition multiple EPA offices, or to impose on the Agency the impossible task of coordinating multiple responses. If affected persons must submit multiple petitions, then each individual office will have an incentive to defer a decision, possibly indefinitely, until sister offices have made their determinations. Further, each office may reject portions of a complaint on the ground that the specific matter in dispute concerns another office, leaving no office responsible for resolving the dispute.

If EPA fails to establish a central point for resolving complaints, then the executive panel that the Agency proposes will be swamped with complaints. The chief information officer will become a full time executive panel chairman and the assistant administrators will be unable to perform their regular duties.

3. "What are appropriate time periods for this process?"

If EPA wants each program office to perform an initial review, that process needs to have a tight deadline (*e.g.,* 10 business days) for both reaching a decision and implementing corrections. OEI deserves a longer period to initially resolve appeals, but in no case should this exceed 90 days. OMB is expected to review agency information collection requests in just 60 days [see 5 CFR 1320.10(b)], and this task is often much more difficult than resolving an information quality complaint. EPA should achieve a performance level at least this good.

4. "Once an appeal is submitted it would be decided by a top EPA official in collaboration with an executive panel. Do you think this is sufficiently objective and efficient to ensure a timely and appropriate response to an appeal?"

OMB's government-wide guidelines call for an objective complaint resolution process. In principle, vesting complaint resolution authority at a political level within the same office that "owns" the information could enhance accountability. However, EPA does not propose any system by which assistant or regional administrators could be held accountable. Therefore, this element of EPA's proposal is fatally flawed and clearly inconsistent with OMB guidelines.

The "executive panel" approach proposed by EPA also does not meet any plausible test of objectivity. It suffers from the same lack of objectivity that fatally wounds the process that precedes it. In also adds a more layer of unaccountability. Group decision-making systems inherently diffuse responsibility away from individuals. Whereas a complainant

denied relief by an assistant or regional administrator at least can identify the person responsible for making the decision, no such identification is possible in a system where decisions are made by committee.

Decision-making authority should be vested in the chief information officer, who should be required to publicly disclose (based on clear criteria established *ex ante*) the reasoning behind each decision. Further, the CIO should specify exactly what relief a successful complainant is entitled to receive and specific deadlines for all affected agency offices to comply. Should any office fail to comply on schedule, a complainant must be able to appeal the office's lack of compliance to the deputy administrator or administrator without reopening the substance of the underlying complaint and obtain immediate relief. In the case of substantive appeals to the deputy administrator or administrator, these officials must be bound by the same *ex ante* criteria and the same obligation to explain the reasoning for a decision. A complaint resolution process that permits decision-making criteria to change or that permits decisions to be made without documentation has no credibility.

As indicated above, the appeals process generally must be flexible enough to permit complainants to appeal any element of a decision, including procedural matters such as jurisdiction and substantive elements perceived or intended as favorable. EPA's process will fail if a complainant can prevail on the merits but lose in implementation. Under EPA's proposed process, this could happen if the designated decision maker agrees with the complainant but uses one device or another to delay or refuse to make corrections. It also could happen if the decision maker agrees with the complainant but authorizes a correction that itself is flawed or otherwise erroneous.